ISBN 1188-4169

Canada Communicable Disease Report

FAX

Vol. 24-17

Date of publication: 1 September 1998

Contained in this FAX issue: *(No. of pages: 5)*

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CANADIAN CONSENSUS CONFERENCE ON A NATIONAL IMMUNIZATION RECORDS SYSTEM

The Canadian Consensus Conference on a National Immunization Records System was sponsored by Health Canada and held in Ottawa on 2-3 March 1998. It was attended by 65 participants* representing key stakeholder groups, including consumers; health-care providers; privacy experts; and federal, provincial, and local public-health officials.

The Consensus Conference followed up on the recommendations of the 1996 Canadian National Immunization Conference which stated that "*an immunization tracking system is urgently needed in Canada*". The participants agreed that Canada should establish comprehensive immunization registries in all provinces and territories within 5 years. Currently, only Prince Edward Island, Ontario, and Manitoba have operational, systematic, province-wide immunization tracking systems. Therefore, it was felt that there was no better time to launch a Canadian National Immunization Records System initiative designed to support the development and integration of immunization registries. The overall goal is that immunization registries will facilitate the control and elimination of vaccine preventable diseases in Canada by ensuring the provision of information and knowledge necessary to achieve the best possible immunization coverage for Canadians. The objectives of immunization registries were identified as follows.

Patient care and individual level objectives

The registries will

- provide current immunization status information to each individual and/or health-care provider as necessary
- identify children due or overdue for immunization
  Registries will notify parents or guardians and supply providers with information necessary to support follow-up.
- provide information to parents or guardians and providers to avoid inappropriate immunization
- provide information to assist providers in determining the relationship between immunization and adverse events and follow individual patients if necessary.

Public-health and surveillance level objectives

The registries will

- provide information on vaccine coverage to program planners and providers, assist in identifying poorly immunized populations and groups, targeting interventions, and evaluating program efforts
- provide information to assist in the control of outbreaks of vaccine preventable diseases
- minimize costs to the health-care (including private providers), public-health, and school systems by providing efficient records management
- provide information that will assist in assuring accountability for effective vaccine use.

The conference was built around a series of eight small group discussions on key issues. The work was supported by issue papers

* **Participants:** B. Abrahamson, B. Adams, M. Bell, V. Beyn[illegible], N. Boulianne, G. Bruce, D. Buckeridge, M. Carew, J. Carsley, S. Castles, M. Castonquay, G. Clements, G. Delage, M. Douville-Fradet, M. Drouin, P. Duclos, J. Eichmanis, E. Ellis, L. Engwer, M. Finkelstein, P. Fotin, T. Freeman, D. Geisbrecht, R. Girardeau, G. Hammond, A. Hanrahan, G. Howe, A. Hukowich, E. Kilbourne, A. King, M. Litt, I. MacDonald Gemmill, J. Manuel, V. Marchessault, J. Mays, M. Mehr, W. Mindell, D. Mowat, T. Murray, M. Naus, C. O'Keefe, M. Poulin, S. Rechner, D. Reynolds, E. Richardson, T. Riley, J. Roberts, H. Robinson, M Sargeant, J. Sayer, R. Schabas, J. Scott, M. Shannon, I. Sinclair, R. Stirling, S. Straughton, L. Sweet, M. Taha, S. Tamblyn, F. Timmerman, H. Turmain, R. Upshur, P.Varughese, J. Waters, C. Whiting.

that were developed in advance of the conference. Four small groups dealt with general issues (Objectives, Barriers, Confidentiality, and Success Factors) on the first day. Four small groups dealt with systems issues (General Systems Issues, Data Elements, Confidentiality, and Reporting Functions) on the second day. Each small group brought a report back to plenary sessions where consensus was reached on the issues. The following recommendations for an effective national immunization registry were made.

Registry components

- Universal enrollment, including the entire target population and all immunization providers
  Canadian immunization registries should include all children in Canada. As a minimum start-up, they should include all children from birth to age 7 years. They should be expanded in short order to include all school-age children. These registries should have the capacity to include other target populations such as travelers, candidates for influenza and pneumococcal immunization, and residents of long-term care facilities. There should be lifelong retention of information.
- Recording all immunization events, with ability to link to information about adverse vaccine reactions and incidence of vaccine-preventable diseases
- Individual provincial and territorial systems, with this level of government providing central support
  The operation of the registries should be locally based, where data are entered and the capacity for generating reports exists. These systems need a common set of data elements and standards, including immunization logic.
- Common elements that are nationally consistent, i.e. consistent within and between provincial and territorial registries
- Ability to interact with other health information systems, including those dealing with disease surveillance and adverse vaccine reactions
- Capacity to draw enrollment directly from birth records, provincial and territorial health insurance enrollment records, school and day-nursery enrollment records, and immigration notifications.

Registry design

- Registries should be based at provincial and territorial levels.
- Registries must be flexible in design and, in particular, be able to accommodate data entry from multiple sources.
- There must be a commitment at a senior level, i.e. Conference of Ministers and Conference of Deputy Ministers, to the concept of registries, a legislative foundation for registries, and the exchange of immunization information.
- Immunization registries are a priority to Health Canada which provides support in terms of developing standards, a clearinghouse function, funding for development and start-up, integration with the National Health Surveillance System, economic analysis of the costs and benefits of registries, and promoting research to improve registry function.
- All provincial and territorial governments should commit to developing and supporting immunization registries, and be prepared to provide adequate on-going operating funds. Compatibility of registries within their province or territory and compatibility with other provinces and territories should be ensured by adhering to national standards. Provincial and territorial governments should make the computerization of local public-health departments and health-care practices a priority.
- All provincial and territorial governments must provide a legislative foundation for immunization registries within provincial public-health and privacy legislation. This legislation should make participation mandatory.
- Public support must be achieved and maintained by ensuring the individual's ability to access their own records, and by providing tangible evidence of benefit through notifications about due and overdue immunizations. Data subjects should only have to give information once. Preserving the confidentiality of information is absolutely essential to maintain public confidence. There should be clear guidelines about how data may be used and acceptable use.
- Privacy interests must be involved at every stage of development and implementation.
- Provider support and participation are critical; providing incentive to providers and partnerships with provincial and territorial medical associations will be required. Providers should be given aggregate reports and should be able to access their own practice data. Operation should be simple, efficient, and user-friendly. There should be relief from client requests for immunization records.
- The National Advisory Committee on Immunization (NACI) should review its immunization guidelines to make them more "programmer-friendly".
- Immunization registries should be developed as a model audit tool for quality improvement, and used for educating health-care providers.
- Registry operators should support the system by regular reporting to policy makers about progress towards coverage targets and by identifying cost savings.
- Registries must support reporting functions that assist in ensuring an efficient immunization system with maximum population coverage.

Next steps

At the end of the conference the following three recommendations were put forward for immediate action.

- Health Canada should establish a National Advisory Group on Immunization Registries to further the agenda laid out in this report. It should have representation from provinces and territories, provider groups, consumers, privacy interests, and immunization

advisory groups (e.g. NACI). Priority should be given to establishing data elements and technical standards, and creating a national clearinghouse function.

- Each province and territory should establish an Immunization Registry Working Group to actively plan and implement a registry. Membership should include public health authorities, providers, consumers and privacy interests. Several provinces already have committees of this kind.
- Tangible support should be available to assist provinces in the development of registries on condition that they conform to national standards and data elements. Based on the contribution from the American federal government in support of a similar initiative, Canada requires a dedicated $25 million for each of the first 2 years of its registry development and a lesser amount thereafter.

Conclusion

Health Canada is in the process of establishing a National Advisory Group on Immunization Registries. The advisory group will have representation from provinces and territories, providers, consumers, privacy interests, and immunization advisory groups. One of its immediate priorities, when it meets in the fall of 1998, will be to develop a strategy on how to further the agenda laid out at the Consensus Conference. Under its authority, smaller working groups will be developed to start the immediate work of standardizing data elements and technical issues, and creating a national clearinghouse function. Regular updates on the National Immunization Records System initiative will be posted on the Health Canada Website at <http://www.hc-sc.gc.ca>.

Any persons interested in participating in the development of the National Immunization Records System, should contact Margaret Litt, A/Head, Surveillance and Technical Support Section, Division of Immunization, Bureau of Infectious Disease, LCDC, Health Canada Tel #: 613-954-1612 (E-mail: margaret_litt@hc-sc.gc.ca). Detailed minutes from the conference are available by contacting the same number.

Source: *Division of Immunization, Bureau of Infectious Diseases, LCDC, Ottawa, ON.*

VACCINE SAFETY RESOURCE MATERIALS FOR HEALTH-CARE PROVIDERS AND THE PUBLIC

The purpose of this article is to suggest materials and references that are available to respond to vaccine safety concerns, and to present a framework for rationally evaluating information from the Internet.

Information on the safety and effectiveness of vaccines is available from many different sources. Regular readers of *Update: Vaccine-Preventable Diseases*, especially those who work in public health and immunization, will be familiar with a number of these sources including the *Canadian Immunization Guide*, and provincial or territorial immunization guidelines, as well as a variety of leaflets and brochures. However, patients and parents of patients who are receiving vaccinations, as well as the general public, generally share limited access to comprehensive immunization-related information. They may receive only simple pamphlets given at the time of an immunization visit or during the perinatal period. This situation is no longer adequate in the evolving climate of the "informed health-care consumer".

The lack of information about the benefits and risks of vaccination has created an "information vacuum". This "information vacuum" is rapidly being filled by materials on vaccines that are often misleadingly critical of and even opposed to vaccination. Materials include several books available at local bookstores and an explosion of Internet sites devoted to denouncing vaccination. Using a combination of intentionally misleading, inaccurate, and false information, readers are urged not to forgo immunization (as this could potentially expose authors of these sites to liability) but to "make up your own mind" after reading the "undisputed facts". The relative ease of access and ready availability of these materials means that patients or parents are increasingly likely to arrive for an immunization visit with printouts and related questions. Responding to the claims of these anti-vaccination Websites or books can be difficult without the availability of targeted resources.

Complacency with what was once a miraculous health intervention that did not need to be questioned must now be replaced with a reaffirmation of the benefits of vaccination over its risks. The need for effective communication about vaccine safety is finally being addressed by several countries as well as the World Health Organization (WHO). Accurate material is becoming increasingly available on the Internet. As new materials are received and evaluated, they will be presented in future issues of *Update: Vaccine-Preventable Diseases*.

Core references for health-care providers

Adverse Reactions

1. Institute of Medicine (Stratton KR, Howe CJ, Johnston RB, eds.). *Adverse events associated with childhood vaccines: evidence bearing on causality*. Washington DC: National Academy Press, 1994.
2. Institute of Medicine (Howson CP, Howe CJ, Fineberg HV, eds.). *Adverse effects of pertussis and rubella vaccines*. Washington DC: National Academy Press, 1991.
3. CDC. *Update: vaccine side effects, adverse reactions, contra- indications, and precautions: recommendations of the Advisory Committee on Immunization Practices (ACIP)*. MMWR 1996;45 (RR-12).

Together, these references form a comprehensive review and overview of the causality relationship between serious adverse events and immunization. An expert committee convened by the Institute of Medicine assessed available literature and outlined conclusions based on strength of evidence. The core material is contained in the two books (1 and 2), with some updates in the *Morbidity and Mortality Weekly Report* (MMWR) (3). These three references are available for browsing on the Internet. All

issues of MMWR are accessible through the United States Centers for Disease Control and Prevention (CDC) Internet site described below. The two books are available for reading (2 now, 1 is anticipated) through the Internet site of the National Academy Press at <www.nap.edu> in the "Reading Room" (select the option to "search" to locate the titles).

Immunization and Vaccine-Preventable Diseases Guides

4. National Advisory Committee on Immunization. *Canadian immunization guide*. 5th ed. Ottawa ON: Health Canada, Minister of Supply and Services, 1998. (In press.)

   The latest edition of the *Canadian Immunization Guide* will be available on the Internet at the Laboratory Centre for Disease Control (LCDC) Website and can be accessed directly from the Division of Immunization Internet site listed below. Several provinces and territories publish immunization guides for public-health clinics or vaccine providers. Readers are encouraged to inquire at their local health units for the availability of guides in their province or territory.

General Vaccine Information and Monographs

5. Gillis MC, ed. *Compendium of pharmaceuticals and specialties*. Ottawa ON: Canadian Pharmacists Association, 1998.
6. Grabenstein JD, ed. *ImmunoFacts: vaccines and immunologic drugs*. St. Louis MO: Facts and Comparisons, 1998.
7. Plotkin S, Mortimer E. *Vaccines*. Philadelphia PA: W.B. Saunders Co., 1994.

   The first two references contain product monographs. The blue "CPS" (5) should be familiar to many as a drug reference but it is not a comprehensive reference for all vaccine products licensed in Canada. *ImmunoFacts* (6) is a three-ring binder of standardized vaccine monographs, routinely updated, that lists all licensed drugs whose action is wholly or largely immunologic in nature. The editors have based most of their selections on Canadian and American products, but have included international immunologic drugs as well. The textbook by Plotkin and Mortimer (7) is a well recognized and well respected reference on vaccines. Although the notations on safety are not as comprehensive as the other sources suggested in this article, it is an excellent overall reference on vaccines and vaccination. A new edition is in preparation.

Books for parents

8. Canadian Paediatric Society. *Your child's best shot: a parent's guide to vaccination*. Ottawa ON: Canadian Paediatric Society, 1997.
9. Offit PA, Bell LM. *What every parent should know about vaccines*. New York NY: Macmillan, 1998.

   For parents who wish to read material that is more complete and more comprehensive than any of the brochures and pamphlets available, these two small books are ideal. The first one (9) is more "sophisticated" and some parents may find it too difficult to digest. The book by Offit and Bell is targeted toward a simpler reading level and is more readily available in bookstores; however, it is written for an American audience. Therefore, some of the data and vaccine information presented may not be relevant. The Canadian Paediatric Society book can be ordered through their Internet site <www.cps.ca> or by calling (613) 526-9397 ext. 245. A table of contents and description of the book is also provided at the site.

Internet Resources

10. Division of Immunization, LCDC:
    Home page <www.hc-sc.gc.ca/hpb/lcdc/bid/di>

    Links to the sites listed here as well as new ones will be added to the section on "Vaccine Safety". There is also a link to the *Canada Communicable Disease Report* where all current National Advisory Committee on Immunization statements are published – statements that serve to update the *Canadian Immunization Guide* between editions.
11. National Immunization Program, CDC:
    Home page <www.cdc.gov/nip>

    This is the starting point of the CDC's vaccine information materials. Documents for the public and health-care provider are continually being added. The site also links to the CDC home page from where access to the MMWR is just a link away. The MMWR publishes statements from the Advisory Committee on Immunization Practices, the parallel to the Canadian National Advisory Committee on Immunization.
12. Immunization Action Coalition:
    Home page <www.immunize.org>

    A nonprofit organization working to boost immunization rates, the Coalition promotes physician, community, and family awareness of, and responsibility for, appropriate immunization of all people of all ages against all vaccine-preventable diseases. The Advisory Board includes many well known experts in the field of immunization.
13. Global Program for Vaccination, WHO:
    Home page <www.who.ch/gpv-safety>

    WHO is beginning to provide more accessible information on the issue of vaccine safety, risk and communications.
14. Institute for Vaccine Safety, Johns Hopkins University, USA:
    Home page <www.vaccinesafety.edu>

    This site is currently under construction, but good material is already available and more will be added before the official launch later in 1998.

Some points to raise when discussing Internet information with patients or parents

The following suggestions should help in counselling readers of Internet information and advising them to be more critical of what is available on an unregulated medium. There is no obligation to be accurate or truthful on the Internet.

Be wary of sites that do not take responsibility for their own posted information. If vaccination is such a controversy and vaccines are so dangerous, then why would there be a disclaimer telling readers that the information is only being provided for information, not to suggest a course of action?

Invoke critical appraisal skills and teach these to parents and patients. Information provided on an Internet site should be referenced with sound scientific papers or books based on scientific evaluations. Responsible use of published papers includes describing any limitations, and does not include taking details out of context. Many sites purportedly use "scientific studies" to prove their points, but misinterpret the real conclusions. Also be wary of findings ascribed to "noted researchers": if they are truly competent and renowned, why would their names not be available to be listed?

Be reminded that conspiracy theories abound. Be wary of people who proclaim that they have discovered the "hidden truth" about the dangers of vaccines, and the "medical-industrial complex" is out to suppress this truth. Why would WHO, along with respected public health, medical, and pediatric authorities around the world want to conspire to harm children? Why would sound research be suppressed, and indeed how does anyone actually suppress a scientifically sound

and important finding anyway? Why would researchers want to withhold publication of their findings?

The motives of the site should be clear. Be wary of sites that denounce vaccination in order to sell an alternative "healthy lifestyle" or a "natural, completely safe alternative". If their "product" is indeed of value, why can it not stand on its own merit?

Ask "Are the statements believable?" Are the findings "too good to be true" (we have the cure for cancer!), or too awful to be true (vaccines are killing millions of children!)? How would such "facts", if true, escape public attention around the world and have to depend on an individual Internet site or single book to be disseminated?

Source: *R Pless, MD, MSc, Division of Immunization, Bureau of Infectious Diseases, LCDC, Ottawa ON. (Adapted from Update: Vaccine-Preventable Diseases 1998;6:28-30).*

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Submissions to the CCDR should be sent to the Editor-in-Chief, Laboratory Centre for Disease Control, Tunney's Pasture, Address Locator 0602C2, Ottawa, Ontario K1A 0L2.

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Price per year:
Base subscription : $80.00 (plus applicable taxes) in Canada; $105 (U.S.) outside Canada.
Premium subscription : $150.00 (plus applicable taxes) in Canada; $175 (U.S.) outside Canada.

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